

REMARKS

After entry of this Amendment, the pending claims are: claims 1-16, 18-32, 34-51, and 55-76. The Office Action dated February 21, 2007 has been carefully considered. Claims 17 and 33 have been canceled without prejudice. Claims 52-54 were previously canceled. Claims 1, 16, 18, 27, 29, 30, and 40 have been amended without prejudice to expedite prosecution. No new matter has been added. The Examiner is thanked for allowance of claims 51 and 55-76. The Examiner is further thanked for the indication of allowable subject matter in claims 14, 19, 20, 38, 43, and 44. Reconsideration and allowance of the present application in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated February 21, 2007, the Examiner:

- rejected claims 1-12, 15-17, 21-23, 27-36, 39-41, and 45-47 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,660,006 to Markworth *et al.* (“Markworth”);
- Rejected claims 1, 11, 16-18, 27, 35-37, and 40-42 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,440,133 to Beale *et al.* (“Beale”);
- Rejected claims 24-26 and 48-50 under 35 U.S.C. 103(a) as being unpatentable over Markworth in view of U.S. Patent No. 5,688,274 to Errico *et al.* (“Errico”);
- Rejected claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Beale;
- Objected to claims 14, 19, 20, 38, 43, and 44 as being dependent on a rejected base claim. Otherwise the subject matter of claims 14, 19, 20, 38, 43, and 44 would be allowable; and
- Allowed claims 51 and 55-76.

INDEPENDENT CLAIM 1

Independent claim 1 has been rejected as being anticipated by Markworth. As amended, independent claim 1 requires, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly for engaging the spinal implant and a release assembly for contacting the longitudinal spinal member; wherein the release assembly comprises a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member being sized and configured to slidably surround at least a portion of the holder assembly.

Markworth discloses a body 200, a slide 300, a sleeve 400 and a trigger 500 wherein the body 200 incorporates a plurality of fingers 206 extending from the second end 204 of the body 200 for engaging the spinal implant. The slide 300 incorporating a pair of holes 308 for engaging the sleeve 400 via screws 112. The sleeve 400 having a groove 418 formed on an end thereof for engaging the orthopedic rod (*i.e.*, the longitudinal spinal member). The slide 300 and the sleeve 400 being channel-shaped and sized and configured to sit on top of the body 200 so that in use, angular displacement of the trigger 500 causes the slide 300, and hence the sleeve 400 which is connected thereto, to move with respect to the body 200, and hence moves the orthopedic rod which is contacted by the sleeve 400 with respect to the spinal implant which is engaged by the body 200.

It is respectfully submitted that Markworth does not disclose, teach, or suggest a tubular member and certainly does not disclose, teach, or suggest a tubular member which is slidably disposed within the holder assembly, which is slidably disposed within the pusher member.

As generally understood by one of ordinary skill in the art, a tubular member means “having the form or shape of a tube.” Tube means “a hollow, usually cylindrical body of metal, glass, rubber, or other material.” (*See* dictionary.com). Markworth discloses a channel shaped slide member 300, thus it is respectfully submitted that Markworth does not disclose, teach or suggest a tubular member as required by independent claim 1.

Even if the slide member 300 of Markworth is interpreted broadly enough to be a tubular member, Markworth discloses a channel shaped slide member 300 (*i.e.*, the tubular member) which is sized and configured to sit on top of the body 200 (*i.e.*, the holder assembly) (*See* column 6, lines 40-44) and a channel shaped slide member 300 which is sized and configured to engage said sleeve 400 (*i.e.*, the pusher member) via screws. Thus, it is respectfully submitted that Markworth does not teach, disclose, or suggest a tubular member that is sized and configured to be slidably disposed within the holder assembly, and a pusher member that is sized and configured to slidably surround at least a portion of the holder assembly. That is, as required by independent claim 1, the holder assembly must engage the spinal implant and must slidably receive the tubular member of the release assembly therein while simultaneously be slidably disposed within the pusher member of the release assembly.

Therefore, it is respectfully submitted that Markworth does not disclose, teach, or suggest all of the limitations of independent claim 1. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Moreover, independent claim 1 has been rejected as being anticipated by Beale. As amended independent claim 1, *inter alia*, requires a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly for engaging the spinal implant and a release assembly for contacting the longitudinal spinal member.

With respect to the Examiner's first interpretation of Beale, it is respectfully submitted that Beale does not disclose a holder assembly that engages a spinal implant and a release assembly for contacting a longitudinal spinal member, wherein the release assembly comprises a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member being sized and configured to slidably surround at least a portion of the holder assembly. That is, as required by independent claim 1, the holder assembly must engage the spinal implant and must slidably receive the tubular member of the release assembly therein while simultaneously be slidably disposed within the pusher member of the release assembly.

It is respectfully submitted that the Examiner's proposed holder assembly 100 does not engage the spinal implant as required by independent claim 1. Rather, the fastener engaging member 80 of Beale engages the spinal implant. Moreover, it is respectfully submitted that the Examiner's proposed holder assembly 100 does not slidably receive the tubular member 80 of the release assembly while

simultaneously be slidably disposed within the pusher member 500 of the release assembly. Rather, the Examiner's proposed holder assembly 100 is slidably disposed about the holder assembly, which engages the spinal implant. Therefore, it is respectfully submitted that even as interpreted by the Examiner, Beale does not disclose, teach, or suggest all of the limitations of independent claim 1. Withdrawal of this rejection (*i.e.*, interpretation) and allowance of independent claim 1 is respectfully requested.

With respect to the Examiner's second interpretation of Beale, it is respectfully submitted that Beale does not disclose a holder assembly that engages the spinal implant and a release assembly for contacting the longitudinal spinal member, wherein the release assembly comprises a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member is sized and configured to slidably surround at least a portion of the holder assembly. That is, as required by independent claim 1, the release assembly comprises a tubular member and a pusher member, wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly.

It is respectfully submitted that the Examiner's proposed release assembly 100 does not include a tubular member and a pusher member, and certainly does disclose a tubular member and a pusher member wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly. Rather, Beale discloses a fastener engaging member 80 (*i.e.*, the holder assembly) for engaging a spinal implant and a reducing member 100 (*i.e.*, the release assembly) for contacting the spinal rod, the fastener engaging member 80 being slidably

disposed within the release assembly 100. Beale further discloses an extension member 500 which can be placed in contact with the reducing member 100. The extension member 500 extending the overall length of the reducing member 100 to enable surgeons to reduce the spinal rod an additional length. As such, it is respectfully submitted that there is absolutely no disclosure, teaching, or suggestion of a tubular member and a pusher member, wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly. At best, Beale discloses a release assembly 100 that is slidably disposed about the holder assembly 80 and a release assembly 100 that is sized and configured to receive the extension member 500 so that, in use, as the surgeon squeezes the actuator assembly 51, the release assembly 100 and the extension member 500 move together, as a single unit, along the outside of the holder assembly 80. The extension member 500 is not slidably disposed about the release assembly 100. Therefore, it is respectfully submitted that as interpreted by the Examiner, Beale does not disclose, teach, or suggest all of the limitations of independent claim 1. Withdrawal of this rejection (*i.e.*, interpretation) and allowance of independent claim 1 is respectfully requested.

For at least the above-identified reasons, it is respectfully submitted that neither Markworth or Beale disclose, teach or suggest all of the limitations of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2-15, and 21-26 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-15, and 21-26 is also respectfully requested.

INDEPENDENT CLAIM 16

Independent claim 16 was rejected as being anticipated by Markworth. As amended, independent claim 16 requires, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly for engaging the spinal implant and a release assembly for contacting the longitudinal spinal member; wherein the release assembly comprises a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member being sized and configured to slidably surround at least a portion of the holder assembly.

As previously described above in connection with independent claim 1, it is respectfully submitted that Markworth does not disclose, teach, or suggest a tubular member and certainly does not disclose, teach, or suggest a tubular member which is slidably disposed within the holder assembly, which is slidably disposed within the pusher member.

In addition, as amended, independent claim 16 requires, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly, a release assembly, and an actuating member operatively associated with the holder assembly and the release assembly so that actuation of the actuating member moves the holder assembly

with respect to the release assembly; wherein the actuating member is a hand grip, the hand grip having a first grip member, a second grip member, a first jaw member, and a second jaw member, the first grip member is pivotally coupled to the second grip member, the first grip member is pivotally coupled to the first jaw member, the second grip member is pivotally coupled to the second jaw member, and the first and second jaw members are operatively connected with the holder and release assemblies, respectively.

Markworth discloses a handle 514, a grip 218 and a trigger 500 wherein the trigger 500 engages the body 200 and the slide 300 so that movement of the handle 514 with respect to the grip 218 moves the slide 300 with respect to the body 200. Markworth further discloses a plurality of teeth 704 formed on the body 200 and slide 300 so that in use as the user squeezes the handle 514 toward the grip 218, the male tooth 708, which extends upwards from the body 200, is moved along the female teeth 704, which are formed in the bottom of the slide 300, so that the slide 300 is held in place with respect to the body 200 at each step along the way.

There is absolutely no disclosure, teaching or suggestion of a hand grip wherein the hand grip includes a first grip member, a second grip member, a first jaw member, and a second jaw member, wherein the first grip member is pivotally coupled to the second grip member, the first grip member is pivotally coupled to the first jaw member, the second grip member is pivotally coupled to the second jaw member, and the first and second jaw members are operatively connected to the holder and release assemblies, respectively.

As an initial matter, contrary to the Examiner's assertion, it is respectfully submitted that teeth 704 in Markworth do not make up a part of the hand grip and thus can not be interpreted as first and second jaw members as required by independent claim 16. Moreover, as amended, the first grip member is pivotally coupled to the first jaw member and the second grip member is pivotally coupled to the second jaw member. There is absolutely no disclosure in Markworth of the handle and grip pivotally engaging the teeth. Rather the teeth are formed on the body and slide, respectively.

Therefore, it is respectfully submitted that Markworth does not disclose, teach, or suggest all of the limitations of independent claim 16. Withdrawal of this rejection and allowance of independent claim 16 is respectfully requested.

In addition, independent claim 16 was rejected as being anticipated by Beale. As amended independent claim 16 requires, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly for engaging the spinal implant; a release assembly for contacting the longitudinal spinal member; and an actuating member; wherein the release assembly comprises a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member being sized and configured to slidably surround at least a portion of the holder assembly.

As previously described above in connection with independent claim 1, Beale does not disclose, teach, or suggest a holder assembly that engages the spinal implant and a release assembly for contacting the longitudinal spinal member, wherein the release assembly comprises a tubular member

and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member is sized and configured to slidably surround at least a portion of the holder assembly. That is, as required by independent claim 16, the release assembly includes a tubular member and a pusher member, wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly.

It is respectfully submitted that the release assembly 100 of Beale does not include a tubular member and a pusher member and certainly does not include a tubular member and a pusher member wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly. Rather, Beale discloses a fastener engaging member 80 (*i.e.*, the holder assembly) for engaging a spinal implant and a reducing member 100 (*i.e.*, the release assembly) for contacting the spinal rod, the fastener engaging member being slidably disposed within the release assembly. Beale further discloses an extension member 500 which can be disposed about the reducing member 100. The extension member 500 extending the length of the reducing member 100 to enable surgeons to reduce the spinal rod an additional length. As such, it is respectfully submitted that there is absolutely no disclosure, teaching, or suggestion of a tubular member and a pusher member, wherein the tubular member is slidably disposed within the holder assembly and the pusher member is slidably disposed about the holder assembly. At best, Beale discloses a release assembly 100 that is slidably disposed about the holder assembly 80 and a release assembly 100 that is sized and configured to receive the extension member 500 so that, in use, as the surgeon squeezes the actuator assembly 51, the release assembly 100 and the extension member 500 move together, as a single unit, along the

outside of the holder assembly 80. The extension member 500 is not slidably disposed about the release assembly 100.

Therefore, it is respectfully submitted that even as interpreted by the Examiner, Beale does not disclose, teach, or suggest all of the limitations of independent claim 16. Withdrawal of this rejection (*i.e.*, interpretation) and allowance of independent claim 16 is respectfully requested.

For at least the above-identified reasons, it is respectfully submitted that neither Markworth or Beale disclose, teach or suggest all of the limitations of independent claim 16. Thus, it is respectfully submitted that independent claim 16 is allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claim 16 is respectfully requested.

Furthermore, as claims 18-20 all depend from independent claim 16, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 18-20 is also respectfully requested.

INDEPENDENT CLAIMS 27 AND 40

Independent claims 27 and 40 were rejected as being anticipated by Markworth. In addition, independent claims 27 and 40 were rejected as being anticipated by Beale.

Independent claims 27 and 40 both require, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly, a release assembly, and an actuating member engaging a portion of the holder assembly and a

portion of the release assembly so that actuation of the actuating member moves the holder assembly with respect to the release assembly and compresses the fingers from a first position to a second position so that the fingers contact the *underside* of the edge of the spinal implant.

It is respectfully submitted that Markworth discloses a body 200 incorporating a plurality of fingers 206 on an end thereof. The fingers 206 including notches 211 for engaging grooves 105 formed in the coupling element 104. It is respectfully submitted that Markworth does not disclose, teach, or suggest fingers which are sized and configured to contact the underside of the edge of the spinal implant.

Similarly, Beale discloses a fastener engaging member 80 incorporating an enlarged distal portion 88 comprising first and second flex arms 90, 92 and prongs 94, 96. The first and second flex arms 90, 92 being sized and configured to contact the fastener F. The prongs 94, 96 having interior surfaces 96c, 96d which are sized and shaped to match the profile of the portion of the yoke Y of the fastener F that is positionable thereagainst. Extending from interior surfaces 96c, 96d are protrusions 96e, 96f, respectively. Protrusions 96d, 96f have a size, shape and depth that allows insertion into an indentation or hole formed in the yoke Y of the fastener F. Thus, it is respectfully submitted that Beale does not disclose, teach, or suggest fingers which are sized and configured to contact the underside of the edge of the spinal implant.

Nonetheless, in an effort to expedite prosecution of the present application, independent claims 27 and 40 have been amended to recite, *inter alia*, a surgical instrument for urging a longitudinal spinal member into a top-loading spinal implant, the instrument comprising a holder assembly having a

proximal end and a distal end, the distal end including an elongated slot; a release assembly having a tubular member and a pusher member, the tubular member being sized and configured to be slidably disposed within the holder assembly, and the pusher member being sized and configured to slidably surround at least a portion of the holder assembly; wherein the tubular member and the pusher member each include a proximal end and a distal end, the distal end of the tubular member includes at least one hole and the pusher member includes at least one aperture, the at least one hole and the at least one aperture being sized and configured to receive at least one pin for securing the pusher member to the tubular member, the pin being sized and configured to be displaceable within the elongated slot of holding assembly.

It is respectfully submitted that there is absolutely no disclosure in either Markworth or Beale of a holder assembly having an elongated slot and a release assembly including a tubular member and a pusher member, wherein the distal end of the tubular member includes at least one hole and the pusher member includes at least one aperture for receiving a pin for securing the pusher member to the tubular member, the pin being sized and configured to be displaceable within the elongated slot of holding assembly.

Therefore, it is respectfully submitted that as, as amended, independent claims 27 and 40 are allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claims 27 and 40 is respectfully requested.

Furthermore, as claims 28-32, 34-39, and 45-50 all depend from independent claim 27 and, as claims 41-44 all dependent from independent claim 40, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 28-32, 34-39, and 41-50 is also respectfully requested.

CONCLUSION

A fee of \$790.00 is believed due for this submission. The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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